

REMARKS

Applicants respectfully request consideration of the foregoing amendments and the following reasons upon continued examination of the present application on the merits.

I. Status of the Claims

No claim amendment is made in this response. Claims 1, 2, 4-22, 25-36, 38-40, 42-44, 46-48 and 50-54 are pending.

II. Rejection of Claims under 35 U.S.C. §102(b)

Claims 1, 2, 4, 8-13, 30-36, 38-40, 46-48 and 50-54 are rejected under 35 U.S.C. §102(b) for alleged anticipation by PCT Publication No. WO 96/20698 by Levy et al. ("Levy"). Applicants respectfully traverse the rejection.

A. The claimed composition is structurally distinguishable from Levy's composition.

The claimed invention is directed to a solid dose controlled release nanoparticulate drug composition comprising: (a) particles of a drug having an effective average particle size of less than about 1000 nm, (b) at least one surface stabilizer associated with the surface of the drug particles, and (c) at least one pharmaceutically acceptable high molecular weight rate-controlling polymer which is integrated in a rate-controlling matrix with the drug or which coats the drug.

The biodegradable controlled release nanoparticles described by Levy are structurally distinguishable from the claimed composition. More specifically, the active agent of Levy is "incorporated, embedded, or entrained" in a polymer matrix. In contrast to the claimed invention, in which a surface modifier is associated with the surface of the drug particle, in the composition of Levy surface modifying agents are "attached to the surface of the polymer core." Levy, page 7, 1st paragraph. As such, Levy's disclosure fails to meet the claim limitation of "at least one surface stabilizer associated with the surface of the drug particles." In fact, it is unlikely

for Levy's surface modifying agent to have direct contact with, let alone associated with the surface of, the active agent because the active agent of Levy is embedded in the polymeric core.

B. Levy's surface modifying agent fails to teach or suggest the surface stabilizer of the claimed invention.

As disclosed in the specification, the surface stabilizer of Applicants' invention functions as a steric hindrance to maintain the small particle size of the active agent by adhering to the surface of the active agent particles. *See* specification, at page 12. In marked contrast, the surface modifying agent of Levy's composition "assist[s] in targeting the nanoparticles to a desired site (*e.g.*, as an antibody) or in retaining the nanoparticles at the site (*e.g.*, as a cell adhesive)" (page 7, lines 5-7). In view of Levy's teaching, one skilled in the art would not have equated the surface stabilizer of the claimed invention with the surface modifying agent of Levy's composition because they have entirely different functions in the respective compositions.

Because the prior art fails to teach each and every aspect to anticipate the claimed invention, Applicants respectfully request withdrawal of the rejection.

III. Rejection of Claims under 35 U.S.C. §103(a)

Claims 1, 2, 4-22, 25-36, 38-40, 42-44, 46-48 and 50-54 are rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Levy in view of PCT Publication No. WO 99/02665 by Liversidge et al. ("Liversidge"). Applicants respectfully traverse the rejection.

The teachings of Levy are discussed *supra*. Liversidge is cited for the alleged teaching of tablets and pharmaceutically acceptable excipients but fails to compensate for the deficiencies of Levy. Accordingly, Applicants respectfully request the withdrawal of the rejection.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By 

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